

REMARKS

It is respectfully submitted that the present response presents no new matter and places this case in condition for allowance. Entry of the response is proper because it places the case in better condition for appeal. Reconsideration of the application in view of the following remarks is requested.

I. Obviousness

Applicants would like to bring to the Examiners attention the Supreme Court decision in *KSR International Co. v. Teleflex Inc.* Here, the Supreme Court, among other things, held that the Federal Circuit erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. Accordingly, Applicants urge Examiner to use current law and correct the record to the extent that Applicants may have argued for a rigid application of the TSM test. See also, Examination Guidelines for Determining Obviousness in the Federal Register/ Vol. 72, No. 195 Wednesday, October 10, 2007.

II. The Rejection of Claims 1, 2, 4-6, 8, 10,11, 13-15, 17 and 19-23 under 35 U.S.C. 103(a)

Claims 1, 2, 4-6, 8, 10, 11, 13-15, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,954,998 to Zhou (hereinafter referred to simply as "Zhou") in view of an article entitled *Polymersomes: Tough Vesicles Made of Diblock Copolymers* to Disher *et al.* (hereinafter referred to simply as "Disher") or *vice versa* (Disher in view of Zhou).

The present disclosure relates to enzymatic compositions including an enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle, wherein the vesicle includes at least 50% of a synthetic polymer as a vesicle forming agent. The use of a synthetic polymer is an aspect specifically recited in each independent claim.

While Zhou discloses using preparations that contain enzyme, vesicles and surfactants such as Pluronics, Zhou is devoid of any suggestion or instruction on how to provide enzyme encapsulated in a vesicle made of synthetic polymer. Zhou describes "oil-core vesicles" and defines them as those surfactant bilayer vesicles which contain emulsified oil drops at the interior of the vesicle. Moreover, Zhou explains in Col. 4 that the term "Vesicle" is used to describe a concentric bilayer (lamella) containing an internal liquid

region. Typically the internal region comprises a water-filled cavity. Zhou also explains the phrase "oil-core vesicle" to particularly distinguish those spherically concentric multilamellar aggregates which contain a hydrocarbon core. Nowhere does Zhou suggest altering the interior of any vesicle to include enzyme. While, at Column 16, Zhou describes colloidal dispersions which may optionally contain certain adjuncts such as buffering agents, chelating agents, antioxidants, enzymes, etc, nowhere is it suggested to place these agents inside the vesicle of Zhou.

Further, Zhou does not specifically teach the claimed enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle, wherein the vesicle includes at least 50% of a synthetic polymer as a vesicle forming agent; and wherein the synthetic polymer is a di- or tri-block-co-polymer composed of monomers selected from the group consisting of ethyleneoxide, propyleneoxide, ethylethylene, acrylic acid and vinyl amine. While Zhou does mention, *inter alia*, non-ionic surfactants such as PLURONICS in Column 12, Zhou explains that the oil-core vesicles of Zhou may be prepared by combining a surfactant and a peracid precursor with an aqueous solvent and shearing the mixture. Nowhere does Zhou describe the relatively high amount of synthetic polymer used as the vesicle forming agent in accordance with the present claims.

Moreover, the examples of Zhou do not illustrate the utilization of enzyme within a vesicle, or relatively high amounts of synthetic polymer as a vesicle forming agent. Applicants' disclosure employs both enzyme within the vesicles, and a relatively high amount of synthetic polymer as a vesicle forming agent. It would be reasonably clear to one of skill in the art that relatively high levels of synthetic polymer is used as the vesicle forming agent in order to create an enzyme surrounding layer as claimed. Zhou fails to illustrate the utilization of enzyme within a vesicle, or describe or suggest a desirability of including relatively high amounts of synthetic polymer.

Discher fails to cure the deficiencies of Zhou and *vice versa*. While Discher does describe tough polymersomes and synthetic thin-shelled capsules, Discher fails to describe or suggest a desirability of including relatively high amounts of synthetic polymer to encapsulate enzyme. Thus, Discher fails to suggest a method that employs encapsulating an enzyme in a uni-lamellar or multi-lamellar vesicle where a synthetic

polymer is used as the vesicle forming agent. More specifically, Discher is devoid of any suggestion to employ enzyme in a polymersome.

In view of these facts, Applicants respectfully submit that there would be no motivation to modify the prior art (Zhou in view of Discher and *vice versa*) to incorporate enzyme in one or more vesicles. For example, one of skill in the art would not be motivated to substitute the oil in the liposome of Discher for enzyme. Claims 1, 2, 4-6, 8, 10, 11, 13-15, 17 and 19-23 are not obvious and reconsideration is urged.

For the foregoing reasons, Applicants submit that the claims as amended overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 1-23 under 35 U.S.C. 103

Claims 1-2, 4-6, 8, 10-11, 13-15, 17 and 19-23 are rejected under 35 U.S.C. 103 as being unpatentable over Zhou in view of Discher (or *vice versa*), further in view of WO 97/24177 (Hereinafter referred to simply as "Lykke"). This rejection is respectfully traversed.

As Applicants note, *supra*, Discher and Zhou fail to suggest a composition or method that employs encapsulating an enzyme in a uni-lamellar or multi-lamellar vesicle where a relatively high amount of synthetic polymer may be used as the vesicle forming agent in accordance with the present disclosure. Thus, the arguments above are herein incorporated by reference in their entirety to the extent that the Examiner has relied on the prior rejection of Discher and Zhou (and *vice versa*) in the present rejection.

Applicants also note that all independent claims were previously amended to require a uni-lamellar or multi-lamellar vesicle. Lykke does not relate to such a vesicle.

Lykke fails to cure the deficiencies of Zhou and Discher. While Lykke may suggest the use of diblock polymers in various compositions, Lykke fails to teach or suggest a composition or method that requires a relatively high amount of synthetic polymer used as the vesicle forming agent in accordance with the present disclosure. For example, Lykke fails to teach enzyme encapsulated in a uni-lamellar or multi-lamellar

vesicle including wherein the vesicle includes at least 50% of a synthetic polymer as a vesicle forming agent; and wherein the synthetic polymer is a di- or tri-block-co-polymer composed of monomers selected from the group consisting of ethyleneoxide, propyleneoxide, ethylethylene, acrylic acid and vinyl amine. Conversely, Lykke includes an encapsulation layer in a web-like or plastic-like structure.

Lykke describes an encapsulation layer resulting from the coacervation or condensation reaction which is randomly cross-linked (i.e., web-like or plastic-like structure). One of ordinary skill in the art would not be motivated to substitute the layers of Lykke with a composition or method that requires a relatively high amount of synthetic polymer used as the vesicle forming agent in accordance with the present disclosure. Accordingly, independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious.

Finally, with respect to Lykke, the Applicants respectfully submit the Examiner has not provided a rationale for this obviousness rejection. Applicants respectfully request a further explanation from the Examiner explaining the Examiner's rationale behind the obviousness rejection. In other words, Applicants respectfully submit that the Examiner has been overly conclusive in making this rejection.

For the foregoing reasons, Applicants submit that the claims as amended overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: December 19, 2007

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